Remarks/Arguments

Reconsideration is respectfully requested. Claims 55-69 and 73 are pending. Claims 55-69 and 73 are rejected.

For the reasons set forth below, Applicants respectfully submit that all pending claims are allowable.

I. Anticipation Rejections

Claims 55-69 and 73 are rejected under 35 USC §102(b) as being anticipated by B. Aussedat, (A user-friendly method for calibrating a subcutaneous glucose sensor-based hypoglycaemic alarm, *Biosensors & Bioelectronics*, Vol. 12, No. 11, pp. 1061-1071, 24 March 1997). See Office Action page 2.

Applicants respectfully disagree and traverse the Examiner's rejections.

In rejecting independent claim 55 (and all pending dependent claims) as anticipated, the Examiner refers to various portions of Aussedat. However, neither the portions of Aussedat relied upon by the Examiner, nor the entire disclosure of Aussedat, teach or suggest the claimed combination set forth in pending independent claim 55 and the dependent claims 56-69 and 73.

As the Examiner is well aware, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); See also, MPEP Section 2131. The Federal Circuit has stated: "the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Accordingly, "the Patent Office has the initial duty of supplying the factual basis for its rejection. It may not . . . resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis." *In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967).

Turning to the Examiner's rejection, the Examiner refers to page 1061, ECU as teaching the claimed continuous glucose sensor and the integrated receiver that receives the data stream from the continuous glucose sensor. See Office Action pp. 2-3. The Examiner then refers to page 1062 and the discussed needle type glucose sensor as teaching the claimed integrated receiver including a single point glucose monitor configured to receive a biological sample from the host and to measure the concentration of glucose in the sample. See Office Action, p.3. The Examiner then refers to FIG. 1 of Aussedat as disclosing the claimed measured glucose concentration including a reference data point. See Office Action, p.3.

As disclosed in Aussedat, however, the needle type glucose sensor described on pages 1062-1063 is a subcutaneous glucose sensor that that provides output (e.g., current signals sampled every 30 seconds) as illustrated in FIG. 1 of Aussedat indicated by the black circles which shows the sensor current in nA over a time period. Nowhere in Aussedat does it teach or suggest an integrated receiver that includes, in addition to receiving data stream from a continuous glucose sensor, a single point glucose monitor which is configured to receive a biological sample to measure glucose concentration in the sample, where the measured glucose concentration includes a reference data point.

On the contrary, Aussedat discloses:

> Once the ECU has recognized two plateaus, *the user is asked* whether the plateaus are valid. *This implies that a blood glucose determination has been successfully performed by another method.*

See Aussedat, Page 1063, right column (emphasis added).

In other words, the ECU of Aussedat does not disclose or suggest the claimed integrated receiver that includes a single point glucose monitor. Furthermore, Aussedat discloses that "the plateau recognition software triggers an alarm when the sensor output has reached a plateau, asking for the determination of blood glucose concentration, which would be used in the calibration procedure." See Aussedat, page 1063, left column. In fact, the ECU in Aussedat is connected to the glucose sensor and

includes a memory to store values of current sampled by the sensor over a time period, and displayed on the LCD of the ECU. As further described in Aussedat, the ECU has calibration software which permits transformation of the current into an estimation of the glucose concentration which is displayed on the LCD. The discussion in Aussedat of experimental validation of the use of its ECU and plateau recognition software further supports the determination of blood glucose concentration using another method, for example, Beckman Analyzer as described on page 1063 of Aussedat.

As understood, Aussedat fails to disclose or suggest the combination set forth in pending claim 55 including, among others, an integrated receiver that receives the data stream from the continuous glucose sensor, wherein the integrated receiver includes a single point glucose monitor, a processor, and a computer readable memory, wherein the single point glucose monitor is configured to receive a biological sample from the host and to measure the concentration of glucose in the sample, the measured glucose concentration including a reference data point.

The deficiencies of the disclosure in Aussedat is equally applicable to the dependent claims of the present application, for each of which, the Examiner's rejection is traversed and the arguments set forth above renewed.

For example, nowhere does Aussedat disclose or suggest rejecting a reference data point obtained when the rate of change of the data stream is above a threshold as set forth in claim 56. In fact, Aussedat teaches determining that the sensor output has reached a plateau, at which time, the software in the ECU triggers an alarm, asking for the determination of blood glucose concentration. See Aussedat, page 1063. There is no teaching, as best can be understood, in Aussedat, where a reference data point is obtained when the rate of change of the data stream is above a threshold, and to reject such reference data point obtained.

Furthermore, turning to the limitation of pending claim 62, Aussedat does not teach or suggest comparing a first reference data point to a second reference data point

to determine whether the first reference data point is clinically acceptable. In fact, Aussedat plainly discloses that "[t]his implies that a blood glucose determination has been successfully performed...." See Aussedat, page 1063. Aussedat does not teach or suggest comparing a first reference data point to a second reference data point, let alone to determine whether the first reference data point is clinically acceptable.

As a further example of the deficiency in the disclosure of Aussedat, in conjunction with the rejection of claims 66 and 67, for example, while the Examiner asserts that Aussedat on page 1065 discloses detecting below 70mg/dL/min, and that 0.25 and 0.5 are less than 70, what Aussedat in fact discloses is a threshold level of 70mg/dL, which is not a rate of change of the level. In fact, it is difficult to imagine, let alone whether feasible or not, a scenario where the glucose level variability is at 70mg/dL **per minute**. Certainly, this is not described nor suggested in Aussedat.

At least for the reasons set forth above, Applicants traverse the Examiner's rejections and respectfully submit that the pending claims are allowable.

Notwithstanding the traversal, claim 55 is amended as set forth above. It is to be noted that the amendment to the claims are made for the sole purpose of advancing the prosecution of the present application and not intended in any way as acquiescence to the propriety of the Examiner's rejections. To this end, Applicants reserve the right to pursue claims of the same or similar scope prior to the amendment set forth herein in one or more continuing applications.

In view of the above, Applicants respectfully submit that the pending claims are allowable.

No Disclaimers Or Disavowals

Amendments to and/or cancellations of the claims are being made without prejudice and solely to clarify issues before the Examiner and/or to advance prosecution of this application and are not intended as a disavowal of any subject matter and do not constitute an agreement or acquiescence to any objection and/or rejection. Accordingly, by this response Applicants do not concede that previously pending claims are not patentable.

Applicants reserve the right to pursue claims to any subject matter supported by the disclosure of this application in one or more continuation and/or divisional applications at a later time, including the subject matter of any pre-amended and/or cancelled claims, including broader and narrower claims, and including any subject matter found to be disclaimed herein or by any prior prosecution (should such subject matter be found to be disclaimed despite Applicants' statement herein of no such disclaimer). Accordingly, Applicants do not make any disclaimers or disavowals of any subject matter supported by the present disclosure.

Applicants' silence with regard to the Examiner's rejections of and/or objections to certain dependent claims constitutes a recognition by Applicants that the rejections and/or objections are moot based on Applicants' amendment or remarks relative to the independent claim from which the dependent claims depend. Such silence does not constitute an acquiescence to any of the Examiner's objections and/or rejections, and Applicants reserve the right to argue the patentability of such dependent claims at any appropriate time.

Remarks and/or amendments, or a lack of remarks and/or amendments, are not intended to constitute, and should not be construed as, an acquiescence, on the part of Applicants: as to the purported teachings or prior art status of the cited references; as to the characterization of the cited references advanced by the Examiner; or as to any other assertions, allegations or characterizations made by the Examiner at any time in

this case. Applicants reserve the right to challenge the purported teaching and prior art status of the cited references at any appropriate time.

In view of the foregoing, Applicants respectfully submit that all pending claims are allowable, and request the Examiner's early examination of the pending claims in the present application. In the event that the Examiner deems a telephonic or in person discussion would be helpful in advancing the prosecution of the present application, Applicants respectfully request the Examiner to contact Applicants' representative at (510) 652-6418, x82.

Respectfully submitted,
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